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April 20, 2004

Dockets Management Branch
Docket Number 03P-0029
U.S. Food and Drug Administration
Room I-23
12420 Parklawn Drive
Rockville, MD 20857

Re: **Comments Regarding Citizen Petition Submitted by the U.S. Stakeholders Group on MDI Transition (Docket Number 03P-0029)**

As a responsible corporation, Honeywell wholly supports the transition from ozone-depleting substances ("ODS") to non-ozone-depleting substances. Over the last ten years, Honeywell has led the transition to non-ODS substances by investing hundreds of millions of dollars to provide its customers with functional, novel, ozone- friendly and economical alternatives to ODS.

Honeywell is aware of the importance of albuterol metered dose inhalers ("MDIs") to asthma patients and is writing this letter in its efforts to ensure that any decision to remove albuterol from the list of essential uses for ODS be made on the basis of the most recent facts available. Therefore, Honeywell hereby submits comments to the January 29, 2003 Citizen Petition by the U.S. Stakeholders Group on MDI Transition ("Citizen Petition"), which requests that the FDA publish a notice of proposed rulemaking to remove albuterol from the list of essential uses for ODS.

Honeywell assures the FDA that it has the ongoing capacity to supply the chlorofluorocarbon propellants("CFCs") necessary for ongoing use of MDIs, including albuterol MDIs, until well into the next decade. Honeywell's business plan includes supporting an orderly transition from CFCs by continuing to supply CFCs for MDIs as long as patient requirements are sufficient to warrant continued production.

I. History of Honeywell CFC Supply

Honeywell has been supplying the MDI industry with propellants for over 20 years. Honeywell currently manufactures CFCs for use in MDIs at two sites: (1) CFC-11 and CFC-12 in Weert, Netherlands; and (2) CFC-114 in Baton Rouge, Louisiana. Although Baton Rouge production of CFC-11 and CFC-12 was suspended in 1995 as part of a production rationalization effort, Honeywell is still capable of producing these two products there.

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II. Certainty of Future Supply

The Citizen Petition, citing previous United Nations Environment Programme ("UNEP") and Technology and Economic Assessment Panel of the Montreal Protocol ("TEAP") reports, claims that there is uncertainty about the future supply of CFCs. While it is true that the Dutch government has indicated to Honeywell that it will not allow production of CFCs at Weert past the end of 2005, the reality is that the major manufacturers of MDIs can and do manage this uncertainty through strategic inventories and supply agreements, which include reasonable notice of supply transition. Honeywell has invested considerable time and effort to minimize any uncertainty regarding the supply of CFCs for MDIs. Honeywell works very closely with the pharmaceutical industry and provides regular updates on Honeywell's production plans.

Anticipating the most logical ways in which the transition may occur, Honeywell is in a position to meet the pharmaceutical industry's demand for CFC production through the following alternatives:

- MDI manufacturers normally carry strategic inventories of CFCs that, coupled with essential-use allowances for 2004 and 2005, should allow them to use Weert-made products until 2008. Honeywell is willing to work with albuterol MDI manufacturers to produce and store enough material from Weert to last them until 2008.

- In addition, Honeywell plans to start production of CFC-11 and CFC-12 at Baton Rouge this year. Honeywell expects to have CFC-11 and CFC-12 available for our customers who wish to start sourcing from Baton Rouge *this year*. This gives MDI manufacturers a new source of CFCs in addition to Weert, enabling albuterol MDI production for as long as necessary.

III. Conclusion

We want to make the FDA aware that concern about unavailability of CFCs should not prompt a decision that bypasses the need for a reasonable transition plan. Honeywell will work with all MDI manufacturers to ensure adequate CFC supplies for any way in which the transition will occur.

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We appreciate the opportunity to make our views known to the FDA. Please contact me if you have any questions or additional information you require on this matter.

Sincerely,

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